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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,628	04/04/2007	Christian Peter Petzelt	02839/46201	8178

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
08/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,628	PETZELT ET AL.	
	Examiner	Art Unit	
	ERNST V. ARNOLD	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/5/09 has been entered.

Claims 1-14 and 20-24 have been cancelled. Claims 15-19 are under examination.

Withdrawn rejections:

Applicant's amendments and arguments filed 6/5/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Claims 13-20 were rejected under 35 U.S.C. 112, first paragraph. Applicant has cancelled and amended the claims. The Examiner withdraws the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/53192 (Hereinafter '192) in view of Bedi et al. (Critical Care Medicine 2003, 31, 2470-2477) and Hasselgren et al. (Intensive Care Med 1986, 12, 13-16).

Applicant claims:

> **15.** (currently amended) A method of ~~protecting~~ reducing apoptotic cell death in endothelial cells of the intestine in sepsis comprising administering to ~~said~~ a human an effective amount of a pharmaceutical preparation comprising xenon or a xenon gas mixture.

Determination of the scope and content of the prior art

(MPEP 2141.01)

'192 broadly teaches the use of xenon or xenon gas mixtures for treating neurointoxications in which the neurotransmitter equilibrium is also disturbed (Abstract and claim 1). The Examiner interprets this to mean methods of using the composition. '192 discloses a preparation that contains **5 to 90%** by volume xenon (claim 12) and a preparation that contains

5 to 30% by volume xenon (claim 13). The preparation can further contain **oxygen and/or nitrogen and/or air** (claim 14 and 17). The preparation has a ratio of xenon to oxygen of **80 to 20%** by volume (claim 15 and see also page 8, second paragraph). A method of producing the preparation by mixing xenon with another gas harmless to humans is disclosed (claims 18 and 19).

Bedi et al. teach the use of xenon as a sedative for patients receiving critical care and teach sepsis and endotoxemia as conditions (title; page 2473, left column and page 2476 conclusion).

Hasselgren et al. teach that septic encephalopathy is characterized by increased level of brain glutamine as well as other brain neurotransmitters (Page 14, Brain amino acids and Brain neurotransmitters). Hasselgren et al. teach altered brain neurotransmitter profile in septic encephalopathy (page 15, left column). Hence, the neurotransmitter equilibrium is disturbed in septic encephalopathy.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and '192 is that '192 do not expressly teach a method of reducing apoptotic cell death in endothelial cells of the intestine in sepsis. This deficiency in '192 is cured by the teachings of Bedi et al. and Hasselgren et al.

2. The difference between the instant application and '192 is that '192 do not expressly teach a method of reducing apoptotic cell death in endothelial cells of the intestine in sepsis wherein the pharmaceutical preparation additionally contains inhalable medicaments.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of '192 as a method of reducing apoptotic cell death in endothelial cells of the intestine in sepsis, as suggested by Bedi et al. and Hasselgren et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because '192 teaches treating neurointoxications and points out glutamate as a neurotransmitter. Hasselgren et al. teaches that the septic condition caused increased glutamate levels which would be a neurointoxication as taught by '192 and thus within the scope of '192. Furthermore, Bedi et al. suggest using xenon as a sedative for patients suffering from sepsis. Since sepsis is correlated with increased neurotransmitters in the brain, then it is obvious to treat this patient population based on the teachings of '192 and the cited references. Since the same amount of xenon is used by '192 as instantly claimed then the method of '192 intrinsically reduces apoptotic cell death in endothelial cells of the intestine. Once the xenon is inhaled then it indiscriminately flows throughout the body and would treat endothelial cells of the intestine.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of '192 with additional inhalable medicaments and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the preparation of '192 is not closed and can contain other inhalable medicaments and it would be

obvious to one of ordinary skill in the art of medicine to co-administer therapeutic agents to treat symptoms of the disorder at hand.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 6:15-3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1616